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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,454	02/08/2005	Monique Berwaer	2004_0980A	2307

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,454	BERWAER ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,6 and 8-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,6 and 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 8/20/2007 and 09/26/07 have been entered.

Response to Arguments

Applicant's arguments with respect to claims 3, 6, and 8 have been considered but are moot in view of the new ground(s) of rejection.

Oath/Declaration

Applicants' Declaration under 37 CFR 1.132 submitted 23 February 2007 was considered again in view of Applicants' remarks. The Declaration compares instantly claimed combination immediate/prolonged release dosage form to the immediate release efletirazine of the art. The declaration shows that the instantly claimed composition has a different release profile from that of the immediate release tablet of the art. However, the prior art teaches the artisan how to make prolonged-release efletirazine dosage forms, and motivates manufacture of dosage forms with prolonged and immediate release efletirazine fractions (see rejections under 35 U.C.C. 103, *infra*). Thus, while the declaration clearly shows that the instant invention is not anticipated by the prior art, it does not show the invention to be unobvious.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites "monocrystalline cellulose," which is not believed to exist. It is possible that "microcrystalline cellulose" was intended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 6, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,043,167 to Rotini et al., in view of DERWENT-ACC-NO 1999-585815 (the '815 reference), US 5,869,479 to Kreutner and US 3,906,086 to Guy et al.

Claim 1 requires a composition having efletirizine as active agent with one immediate release and a second sustained release fraction, wherein the fraction of drug in the immediate release and extended release fraction is defined by ratios and equations in the form of a two layer tablet that is a single-daily dose tablet, wherein the extended release fraction contains a matrix-type excipient and the immediate release

fraction contains a diluent, binder, disintegrating agent, lubricant, flow enhancer, taste-masker, flavoring or coloring.

Claim 6 specifies that the prolonged release fraction contain less than 5% basifying agent. Claim 8 further specifies the amount of active in the dosage form, and claim 9 further limits the ratio of immediate release efletirizine to prolonged-release efletirizine.

Rotini teaches formulations that have an immediate release fraction and a controlled release fraction (col. 1, lines 60 – 66, examples). An exemplified drug is diclofenac (example 2). In the controlled release portion the drug is mixed with ethylcellulose, a matrix-type excipient (*id.*) The immediate release portion has lactose, which is a binder (*id.*) Granules of the immediate release formulation and granules of controlled release formulation are made separately, mixed, and formed into tablets by pressing (*id.*) The resulting tablets are suitable for once a day administration (col. 2, lines 1 – 5).

What is missing is:

1) The claimed drug efletirizine; and

2) The claimed two-layer tablet; and

3) The claimed amount of efletirizine in the immediate and prolonged release portions.

The '815 reference teaches that the drug of Rotini, diclofenac, is used for treating rhinitis (title).

Kreutner teaches that efletirizine, the drug of instant claims, is used for treating rhinitis. (claims 1 and 4).

Guy teaches a combination controlled and immediate release dosage form (abstract). The dosage form is made by providing prolonged release particles and immediate release particles and forming them into a two-layer tablet (abstract).

It would be prima facie obvious to a person of ordinary skill in the art at the time of the invention to substitute efletirizne for diclofenac in the invention of Rotini. The motivation is that both drugs are used for the same purpose, namely for treating rhinitis. Because the two drugs both treat the same disease, the artisan would enjoy a reasonable expectation of success.

It would be further obvious to make a two-layered tablet, with one layer having the immediate release and another having prolonged release, instead of the mixed tablet of Rotini. Since Guy recognizes that two-layered tablets with prolonged and immediate release layers serve the same purpose as the single layered tablet having mixed prolonged and immediate release granules of Rotini, the artisan would understand that the two forms are functional equivalents in the art, and would choose that form which was most convenient or efficient depending on the intended use of the final product. The artisan would enjoy a reasonable expectation of success in such manipulations.

With respect to the amount of efletirizine in the immediate release and controlled release layer, this is a matter of dosing, which is mere optimization that is routine in the

pharmaceutical arts. The artisan enjoys a reasonable expectation of success at optimization of such parameters.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,043,167 to Rotini et al., in view of DERWENT-ACC-NO 1999-585815 (the '815 reference), US 5,869,479 to Kreutner, US 3,906,086 to Guy et al., and in further view of US 6,274,168 to Addicks et al.

Claim 10 requires am immediate release fraction comprising lactose, "monocrystaline [sic: microcrystalline] cellulose", colloidal silica and magnesium stearate, and a prolonged release fraction containing the above excipients and HPMC and dibasic calcium phosphate.

The teachings of Rotini et al., the '815 reference, Kreutner and to Guy et al. have been discussed in part above.

Rotini also teaches excipients such as microcrystalline cellulose, lactose, magnesium stearate, and silica gel (colloidal silica), for use in either or both fractions of the dosage form. Col. 3, lines 1 – 12.

Addicks teaches that HPMC is commonly mixed with colloidal silica and magnesium stearate as a binder (example 3), and that dibasic calcium phosphate and microcrystalline cellulose are equivalent diluents in the art (claim 22).

It would be prima facie obvious to a person of ordinary skill in the art at the time of the invention to include the additional excipients HPMC and dibasic calcium phosphate, because these are merely common inactive diluents and binders, which are

combined with other materials to perform the same, predictable function that the perform in the art. The artisan would enjoy a reasonable expectation of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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